

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 18, 2017

Kevin Kutcel Agent for sBioMed LLC 1272 South 1380 West Orem, UT 84058

Subject: Label Amendment – Adding Claims

Product Name: Peradox HC Solution Part A

EPA Registration Number: 84545-4 Application Date: June 21, 2017 Decision Number: 531976

Dear Mr. Kutcel:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Terria Northern by phone at 703-347-0265, or via email at northern.terria@epa.gov.

Sincerely,

Zeno Bain, Product Manager 33 Regulatory Management Branch I Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure: Approved label



PERADOX HC SOLUTION Part A (STERIPLEX SD+ Part A)

BEFORE USING THIS PRODUCT, READ THIS ENTIRE LABEL CAREFULLY

PERADOX HC MIXED SOLUTION is a two-part system and, when Part A and Part B are combined create an effective Sterilant/Sporicide, Tuberculocide, and Bactericide.

ACTIVE INGREDIENT:

 Silver
 00.03%

 Inert Ingredients
 99.97%

 Total
 100.00%

ACCEPTED

Dec 18, 2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 84545-4

CAUTION

KEEP OUT OF REACH OF CHILDREN READ ENTIRE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

[ACTIVATE PRIOR TO USE.] [READ THIS ENTIRE LABEL AND ATTACHED INSERT CAREFULLY.]

[SEE ATTACHED INSERT FOR ADDITIONAL PRECAUTIONARY STATEMENTS]

[REFER TO SIDE PANEL FOR COMPLETE ACTIVATION INSTRUCTIONS.]

[READ ATTACHED INSERT FOR COMPLETE DIRECTIONS FOR USE]

E.P.A. Reg. No. 84545-4

E.P.A. Est. No. 84545-UT-001

Net Contents: (as indicated on Container)

Questions? Comments? Call 1.888.234.6142 Or visit<u>www.steriplex.com</u>



PERADOX HC MIXED SOLUTION is a two part system. When PERADOX HC SOLUTION PART A and PERADOX HC ACTIVATOR SOLUTION Part B are combined; create an effective Sporicide, (Sterilant), (Disinfectant), (Antibacterial), and (Deodorizer)

Kills, (destroys), (eliminates) 99.999% of the following germs: *Bacillus subtillus, Clostridium sporogenes, Mycobacterium bovis* (at 20° C), *Pseudomonas aeruginosa, Salmonella enterica, and Staphylococcus aureus.*

When used as directed, PERADOX HC SOLUTION PART A is effective against the following pathogens on hard non-porous, non-food contact surfaces:

As a Sporicide: Bacillus subtillus

Clostridium sporogenes

As a Tuberculocide: Mycobacterium bovis (Tuberculosis) (at 20°C)

As a Bactericide: aureus (Staph)

A Proven Sporicidal Disinfectant

- PERADOX HC MIXED SOLUTION is an effective sporicide on hard, non-porous surfaces within the medical industry.
- Kills, (destroys), (eliminates) 99.999% of the following germs: Bacillus subtillus, Clostridium sporogenes, Mycobacterium bovis (at 20° C), Pseudomonas aeruginosa, Salmonella enterica, and Staphylococcus aureus.

Pseudomonal aeruginosa (Pseudomonas) Salmonella enterica (Salmonella) Staphylococcus

- Achieves FAST, broad-spectrum PATHOGEN KILL
- Kills Bacillus subtillus, Clostridium sporogenes, Mycobacterium bovis (at 20°C) (at 68°F), Pseudomonas aeruginosa, Salmonella enterica, Staphylococcus aureus
- PERADOX HC MIXED SOLUTION is a broad spectrum Sporicide (Disinfectant)
 (Sterilant) (Antibacterial) (Deodorizer), proven to kill (destroy) (eliminate)
 (deodorize) Bacillus subtillus, Clostridium sporogenes, Mycobacterium bovis (at 20°
 C), Pseudomonas aeruginosa, Salmonella enterica, Staphylococcus aureus, on nonporous hard surfaces.

Hospital and Healthcare Applications: PERADOX HC MIXED SOLUTION is for use in the disinfection of hard, non-porous surfaces in health care settings such as Hospitals and other areas where control of cross contamination is required including: Medical Clinics, Dental Offices, Ophthalmology, Optometry, Blood Collection and Donation Centers, Hospital Central Service Areas, Nursing Homes, Hospices, Rehabilitation Orthopedics, Physical Therapy, Respiratory Physician Radiology, Anesthesia, Laboratories, Cath Labs, Pediatrics, Recovery Rooms Surgery. Critical Care Areas: Emergency Rooms (ER), Intensive Care Units (ICU), Neonatal Intensive Care Units (NICU), Pediatric Intensive Care Units (PICU), Isolation Units, and Surgery. Use Sites: Autoclaves, baskets, bed pans, railings, blood glucose monitors, cabinets, carts, chairs, counters, door knobs and handles, drawer pulls, exam tables, examination gurneys, incubators, infant incubators care cribs, IV poles, lighting fixtures, machines, mammography equipment compressor plates, pails, patient monitoring equipment, physical therapy respiratory shower stalls, stethoscopes, stools, stretchers, telephones, toilet exteriors seats, ultrasound transducers probes, walkers, wheelchairs other hard, non-porous and water sensitive surfaces.



Emergency and First Responder Applications: PERADOX HC MIXED SOLUTION is for use in the disinfection of hard, non-porous surfaces in Ambulances, Police, and Fire, Emergency and First Responder Vehicles and other areas where control of cross contamination is required. Use Sites: CBRN PPE's, SCBA's, ventilation and airway equipment, monitoring defibrillation resuscitators, immobilization devices, communication wheeled cots, folding stretchers, stair chairs, injury prevention IV poles, roof hooks, intravenous arm boards, cardiac nebulizers, cellular phones other electronics, extrication equipment hard, non-porous, water sensitive surfaces listed on this label.

Public Space Applications: PERADOX HC MIXED SOLUTION is for use in the disinfection of hard, non-porous surfaces in [Schools] [Transport vehicles] [buses] [cruise ships] Hotels, Motels, Cruise Ships, Restaurants, Trains, Airplanes, Subways, Buses, Offices, Beauty Salons, Barber Shops, Restrooms, Public Rest Stops, Prisons, Jails, Correctional Facilities, Military & Other Barracks and other areas where there is the close proximity of people and/or where skin or clothing may come into direct contact with hard, non-porous surfaces contaminated with the community-acquired pathogens listed on this label. Use Sites: Seats, benches, stools, arm rests, table trays, railings, toilet surfaces, sinks, faucet fixtures, handles, counter tops, tubs, showers, glazed tiles, door knobs, scales, mirrors, window sills, cabinets, floors, walls and other hard, non-porous surfaces listed on this label.

School and University Applications: PERADOX HC MIXED SOLUTION is for use in the disinfection of hard, non-porous surfaces in School Premises, College and University Premises, Amateur and Professional Sports
Facilities, Athletic Stadiums and Arenas, Field Houses, Gyms, Athletic Facilities, School Buses, Whirlpools,
Spas, Lockers, Restrooms, Fitness Centers and other areas where there is the close proximity of people and/or where skin or clothing may come into direct contact with hard, non-porous surfaces contaminated with the community-acquired pathogens listed on this label. Use Sites: Personal protective safety equipment, athletic helmets, wrestling headgear, boxing half mask respirators, full face breathing apparatus, gas masks, goggles, spectacles, shields, hearing protectors, ear muffs, mats, gymnastic exercise weight machines, aerobic training tables, seats, benches, stools, arm rests, table trays, railings, toilet surfaces, sinks, faucet fixtures, handles, counter tops, tubs, showers, glazed tiles, door knobs, scales, mirrors, floors, walls and other hard, non-porous surfaces listed on this label.

Home Applications: PERADOX HC MIXED SOLUTION is for daily use in the cleaning and disinfection of hard, non-porous surfaces in the home. Homes, Condominiums and Apartments: Use Sites: Hardwood floors, tile floors and linoleum floors, Kitchen and Bathroom countertops, Bathroom shower, Bathroom tub, sinks, sink handles, toilets, cabinets, glass windows, window sills, Computers, Computer keyboards, television remote(s), door knobs, trash cans, refrigerator, and other hard, non-porous surfaces listed on this label.

Nursery and Daycare Applications: PERADOX HC MIXED SOLUTION is for use in the disinfection of hard, non-porous surfaces in **Nurseries and Daycare Centers**. **Use Sites:** Changing tables, cribs, bassinets, toys, toy boxes, riding bath play pens, activity centers, sets, table & chairs, strollers, baby car seats, reception desks, trash cans, diaper pails and other hard, non-porous surfaces listed on this label.

Veterinary Applications: PERADOX HC MIXED SOLUTION is for use in the disinfection of hard, non-porous surfaces in Veterinary Clinics, Animal Hospitals, Animal Shelters, Kennels and Animal Life Science Labs, Animal Laboratories, Tack Shops, Pet Shops, Zoos, Pet Animal Quarters, Stables, Farms and Pet Grooming and Breeding Establishments. Use Sites: Operating tables, kennel runs, cages, sink tops, equipment, utensils, instruments, kennels, stables, stalls, catteries, furniture, walls, floors and animal transportation vehicles will deodorize those areas that are generally hard to keep fresh smelling such as garbage storage areas, empty bins and cans, and any other hard, non-porous areas which are prone to odors caused by microorganisms.

PERADOX HC MIXED SOLUTION is for use in the disinfection of hard, non-porous surfaces in **Livestock Premises, Poultry Premises, Poultry Hatcheries and Animal Housing Facilities**. **Use Sites:** Egg receiving area,



tray dumping egg holding chick setter room, hatchery trays, buggies, racks, flats, processing loading poultry buildings, ceilings, sidewalls and floors.

PERADOX HC MIXED SOLUTION is for use in the sanitation of hard, non-porous surfaces in **Swine Premises**. **Use Sites:** Farrowing barns and areas, dressing plants, blocks, loading equipment, creep area, hauling equipment, nursery and chutes.

PERADOX HC MIXED SOLUTION is for use in the sanitation of hard, non-porous surfaces in **Animal Farms. Use Sites:** Mangers, non-food contact surfaces of feed racks, troughs, automatic feeders, fountains and waterers, forks, shovels, scrapers, floors, walls, all other hard, non-porous in barns, pens, and stalls, chutes facilities fixtures occupied or traversed by animals. This product is not to be applied to food contact surfaces. If food contact surfaces are accidentally contaminated, the surface should be cleaned and rinsed with potable water.

Morgue and Mortuary Applications: PERADOX HC MIXED SOLUTION is for use in the disinfection of hard, non-porous surfaces in Morgues, Mortuaries, Funeral Homes and Funeral Parlors.

Refrigeration Applications: PERADOX HC MIXED SOLUTION is for use in the disinfection of hard, non-porous surfaces on **Coils and Drain Pans of Air Conditioning and Refrigeration Equipment and Heat Pumps**.

PERADOX HC MIXED SOLUTION is effective and for use as directed on hard, non-porous surfaces: stainless steel including titanium-coated and medical grade stainless steel, chrome, plastic (vinyl, LD and HD polyethylene, and polypropylene), silicone rubber, metal, Formica, medical tubing, vinyl rubber, laminated surfaces, glass, acrylic plastic, Plexiglas®, sealed fiberglass, glazed ceramic, glazed enamel, glazed porcelain, Corian®, sealed granite, sealed limestone, sealed marble, sealed slate, sealed stone, sealed terra cotta, sealed terrazzo, and sealed finished woodwork.

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABEL/NG.

MIXING DIRECTIONS FOR ACTIVATION

PERADOX HC MIXED SOLUTION (Part A) is formulated as one component of a two-part system and therefore must not be used alone as a disinfectant or sterilant without activating. Activate PERADOX HC MIXED SOLUTION prior to use by pouring the contents of the PERADOX HC MIXED SOLUTION (Part B) (Activator Solution) small container into the PERADOX HC MIXED SOLUTION (Part A) large container as instructed below:

- 1. Using appropriate personal protective equipment (PPE), remove the cap on the PERADOX HC MIXED SOLUTION (Part A) large container to expose the opening;
- 2. Obtain the PERADOX HC MIXED SOLUTION (Part B) small container and remove the child protective cap. CAREFULLY pour the entire content of the PERADOX HC MIXED SOLUTION (Part B) small container into PERADOX HC MIXED SOLUTION Part A large container.
- 3. Replace cap on the empty PERADOX HC MIXED SOLUTION (Part B) small container and discard as directed;
- Replace cap on the PERADOX HC MIXED SOLUTION (Part A) large container and shake or mix for approximately 15 seconds to combine the solution. PERADOX HC MIXED SOLUTION Activated Solution is now Ready-to-Use as directed.
- 5. Mark the activation date on the product use container using a permanent marker. Once Part A and Part B are mixed, PERADOX HC MIXED SOLUTION mixed solution can be used as a sporicide for ten (10) days and as a disinfectant for forty (40) days. Dispose of any Solution that has exceeded this timeframe post



activation.

Application Methods - For use on Hard, Non-Porous, Non-Food Contact Surfaces PERADOX HC MIXED SOLUTION can be applied to surfaces by conventional, spray, mopping, cloth) or sponge method.

To Fill or (refill) empty spray bottle:

- 1. Remove trigger sprayer (or cap) from empty bottle.
- 2. Unscrew cap (or open spigot) and pour contents into empty bottle.
- 3. Replace trigger sprayer (or cap) and use as instructed

Refill sprayer only with PERADOX HC MIXED SOLUTION.

Cleaning and Deodorization Directions - Pre-clean surfaces prior to application of the activated product.

- 1. Apply a generous amount of the using a cloth, mop or spray device so as to thoroughly wet the surface to be cleaned.
- 2. Allow surfaces to remain wet for 30 seconds.
- 3. For cleanup, rinse the surface(s) with clean cloth or sponge several times with potable water.
- 4. Prepare a fresh solution when it becomes visibly dirty or diluted.

Disinfecting Directions

As a Disinfectant - Pre-clean surfaces prior to application of the activated product.

- 1. Thoroughly apply the solution to the target surface(s) using a prescribed method covering the surface(s), until wet, of product at room temperature.
- 2. The product must remain wet on the surface(s) for 5 minutes.
- 3. For cleanup, rinse the surface(s) with a clean cloth or sponge several times with potable water.

As a Tuberculocide - Pre-clean surfaces prior to application of the activated product.

- 1. Thoroughly apply the solution to the target surface(s) using a prescribed method, covering the surface(s), until wet, of product at room temperature.
- 2. The product must remain wet on the surface(s) for 15 minutes.
- 3. For cleanup, rinse the surface(s) with a clean cloth or sponge several times with potable water.

Application Methods - For use with non-electrical or non-critical/semi-critical Medical Devices

As a Sporicide (Sterilant) - Pre-clean equipment surfaces prior to immersing equipment. Dismantle devices prior to pre-cleaning, if necessary.

- 1. Pour desired amount of solution into a tray or receptacle that will hold the targeted items and allow for complete immersion in solution.
- 2. Immerse equipment or targeted items for a minimum of 180 minutes. Transfer equipment or targeted items to a rinse bath to remove the solution.
- 3. Dipping them a couple of times into the rinse bath will thoroughly remove any solution.
- 4. Place on a clean surface to allow items to air dry prior to reuse.

SBIOMED®

Toll Free: 801 922 1111 www.steriplex.com



As a Disinfectant - Pre-clean equipment surfaces prior to immersing equipment. Dismantle devices prior to pre-cleaning, if necessary.

- 1. Pour desired amount of solution into a tray or receptacle that will hold the targeted items and allow for complete immersion in solution.
- 2. Immerse equipment or targeted items for a minimum of 5 minutes. Transfer equipment or targeted items to a rinse bath to remove the solution.
- 3. Dipping them a couple of times into the rinse bath will thoroughly remove any solution.
- 4. Place on a clean surface to allow items to air dry prior to reuse.

As a Tuberculocide - Pre-clean equipment surfaces prior to immersing equipment. Dismantle devices prior to pre-cleaning, if necessary.

NOTE: The following language will be printed on the label of products intended to be sold to health facilities:

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the human body, either into or in contact with the bloodstream, or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not normally penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION - Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking, and chewing gum, using tobacco or using the toilet. Harmful if absorbed through skin. Remove and wash contaminated clothing before reuse.

PHYSICAL OR CHEMICAL EFFECTS

Minimal corrosion effects may occur with natural rubber and soft iron products. Stainless steels, plastics and polymers exhibit no corrosive effects. Never bring mixture in contact with other sanitizers, cleaners or organic substances. This product is not flammable or explosive.

ENVIRONMENTAL EFFECTS

This product is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters, unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.



FIRST AID FOR	
PERADOX HC MIXED SOLUTION	
IF IN EYES	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing. Call a poison control center or physician for treatment advice.
IF ON SKIN	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20
OR	minutes. Call a poison control center or physician for treatment advice.
CLOTHING	
Have the product container with you when calling a poison control center or going for treatment.	
FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-222-1222	

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage

Store in a dry, cool area and away from direct sunlight. Do not double stack pallets. Use first in, first out storage system.

Pesticide Disposal

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

Container Handling and Disposal

Nonrefillable container: Do not reuse or refill this container.

Clean container promptly after emptying. Offer for recycling if available or reconditioning if appropriate.